



U.S. CONSUMER PRODUCT SAFETY COMMISSION WASHINGTON, DC 20207

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RADM William Stokes
Director
National Institute of Environmental Health Sciences
Interagency Center for the Evaluation of Alternative
Toxicological Methods
P.O. Box 12233
Research Triangle Park, N.C. 27709

Dear RADM Stokes:

We are hereby informing you, as required by the ICCVAM Authorization Act, that the U.S. Consumer Product Safety Commission (CPSC) voted unanimously on January 5, 2009 to not recommend the use of the five test methods for pyrogenicity testing. Since parenteral drugs are not within the jurisdiction of the CPSC and since there are no requirements in any of the CPSC Acts or regulations requiring detection of Gram-negative endotoxins, the recommendations for the use of these tests are not relevant to CPSC testing requirements or needs. The briefing package that the CPSC staff sent to the Commission can be found on the CPSC website (www.cpsc.gov) in the Library (FOIA) section at http://www.cpsc.gov/library/foia/foia09/brief/iccvam.pdf

Sincerely,

Todd Stevenson